*This template is for a* ***Prospective cohort study design****. One of the advantages of prospective studies over retrospective designs is more control of which variables are measured and how they are measured. One disadvantage of prospective studies is that to get 10 years of follow-up, you need to hang around for 10 years. The holiest of all research designs, of course, is the randomized controlled trial. In general, this is the best way to compare two treatments with one another. Common drawbacks to these designs are their expense and the length of time it takes to run them. Additionally, sometimes it is not ethical to conduct a study as a randomized controlled trial. Be sure to contact the Research Navigator for advice on selecting your study design. The IRB will use this protocol to do their review. Please reference sections in this document to complete the IRB application.*

**Title**

(Descriptive title; keep it tight, no 100 word titles)

**Investigators:**

**Version Date** (e.g., the date the protocol was created)

**Significance/Background:** Using the literature, establish any previous work related to your research question. This section should describe the gaping hole in the literature and how your specific aims will attempt to address it. **Make sure to cite your references in this section!**

***Example:***

*Median sternotomy is a common method of access for cardiac procedures. While this approach aids in exposure, a potential risk is post-sternotomy mediastinitis which has a high mortality rate.1 Numerous measures have been taken to prevent infection and sternal dehiscence. The standard of care with respect to routine post-sternotomy closure is cerclage wiring. Recently the use of rigid plate osteosynthesis has been described as an alternative procedure for the prevention of post-sternotomy infection, particularly in high risk patients.2-5 However, no study has randomized high-risk sternotomy patients for direct comparison of cerclage wiring versus plating.*

**Objective(s):** Identify the specific aim(s) for your study.

***Example:*** *To determine if the use of rigid plate osteosynthesis in median sternotomy patients decreases the incidence of sternal dehiscence and/or mediastinitis, relative to closure with cerclage wiring.*

***Primary Outcome Variable(s):***Describe primary outcomes variables for the study.

***Example:*** *Incidence of wound dehiscence and mediastinitis*

***Secondary Outcome Variable(s):***Describe secondary outcomes variables for the study.

***Example:*** *Length of stay, admission to ICU*

***Setting/Resources for the Study:*** Describe where the research will take place. This includes both the setting for the research, as well as the location of any of the patient records to be obtained. You will also need to describe the capability of the investigators to perform the research, as well as the timeframe for the study.

***Example:*** *General Hospital will be the setting for the surgeries, while Baby Grand Pals will be the setting for subject recruitment. Subjects will be enrolled by Ms. Helotes and Ms. Seguin. The surgeries will be performed by Dr. Eeny, Dr. Meeny, or Dr. Moe. The electronic medical record will be accessed by Dr. Norple and Ms. Agincourt to obtain the necessary information. The investigators have all participated in research at General Hospital previously and have successfully completed the CITI program. The timeframe set for this study is five year.*

***Study Design:*** Describe the study design.

***Example:*** *Prospective, randomized, non-blinded*

***Study Subjects:*** Describe where you will obtain your subjects and the specific inclusion and exclusion criteria used.

***Example:***  *All patients >18 years of age presenting to General Hospital undergoing a median sternotomy being performed by a Baby Grand Pals physician and considered high risk will be randomized to closure with either circlage wiring or sternal plating. High risk patients have 3 or more of the following risk factors: chronic obstructive pulmonary disease, renal failure, morbid obesity (BMI > 30), immunosuppression, acquired/concurrent infection, diabetes, chronic steroid use, transverse sternal fractures/off midline sternotomy (intraoperatively), long cardiopulmonary bypass, chest wall radiation and/or reoperative surgery. Patients with a history of mediastinitis will be excluded.*

***Subject Recruitment/Screening/Consent:*** Describe how the subjects will be recruited into the study.

***Example:*** *Patients will be recruited/consented by a nurse (Ms. Helotes or Ms. Seguin) at Baby Grand Pals during a routine office visit to discuss their pending surgery. This will take place in a private consultation room to ensure privacy and should take approximately 10-15 minutes. In order to minimize coercion, it will be made very clear to patients that their participation is strictly voluntary and that choosing not to participate will in no way affect their future care at Baby Grand Pals.*

***Study Procedures:*** This section basically describes methods for obtaining your data and descriptions/definitions of your variables.

***Example:*** *Cerclage wiring and sternal plating are FDA approved, currently in use at General Hospital, and both are considered standard of care.*

*Patients will be randomized to closure with either cerclage wiring or sternal plating. The randomization schedule will be set-up using an excel spreadsheet. After each patient is consented, the randomization schedule will be checked and the data sheet with the type of closure to be used will be placed in the patient chart.*

*Data collected from the chart will include patient demographics, operative technique, revision rates, complications (see data sheet for complete list).*

*Standard of care follow-up will occur at one month with the physician who performed the closure.*

*Complications will be tracked for two years. A tracking tool will be attached to the patient’s chart.*

*The information to be obtained in this study has not been requested by the FDA nor will results from this study be provided to them.*

***Early Withdrawal of Subjects:*** Describe when and why subjects may be withdrawn from the protocol, and what will happen to their previously collected data.

***Example:*** *A patient may be withdrawn from the study prior to the expected completion of that subject for failure to adhere to protocol requirements, or subject consent withdrawal. Patients may choose to withdraw from the study at any time. Data that have already been collected on these patients will still be used.*

***Statistical Plan* *(please don’t struggle with this section, staff are available to help write this up)***

***Sample Size Determination:*** Describe the statistical methods for determining the sample size for the study (reason for choice of sample size).

***Example:*** *The primary outcome variable is the rate of mediastinitis. If we assume a 10% rate in the cerclage group and a 0% rate in the plating group, α=0.05 and β=0.20, we will be able to demonstrate a significant effect with 80 subjects in each group, using the two-tailed 2 test. Incorporating a 10% drop-out rate, we will need 178 patients for this study.*

***Statistical Methods:*** Use this section to provide a thorough description of the statistical tests that will be used in the analysis of your data.

***Example:*** *Quantitative data will be expressed as the mean+SEM, while nominal data will be expressed as a percentage. Quantitative data for the two treatment groups will be compared using the t-test, while nominal data will be compared using the two-tailed 2 test. Significance will be assessed at p<0.05.*

***Potential Benefits:*** Describe any potential benefits associated with participation in the study.

***Example:*** *While nothing can be guaranteed, the hypothesis is that patients in the plating group may experience less wound dehiscence and/or mediastinitis. The patients may not benefit from their participation in this study. Their participation in this study will enable the investigators to compare sternal plating to cerclage wiring in median sternotomy patients.*

***Adverse Events:*** Describe any possible risks associated with the study procedures.

***Example:*** *Sternal Plating: wound dehiscence, sternal non-union, infection, plate exposure, sternal fracture; Cerclage Wiring: wound dehiscence, sternal non-union, infection;*

*The only anticipated severe adverse event is mediastinitis*

***Recording of Adverse Events:***

***Example:*** *At each contact with the subject, the investigator will seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events will be recorded immediately (e.g., signs, symptoms, abnormal diagnostic procedures). The clinical course of each event will be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause.*

***Reporting of Serious Adverse Events***

***Example:*** *Reports of all serious adverse events (including follow-up information) will be submitted to the WMed IRB within five business days. Copies of each report and documentation of WMed IRB notification and receipt will be kept in the Investigator’s records.*

***Data and Safety Monitoring Plan***

***Example:*** *The Principal Investigator will oversee the safety of the study. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan.*

*This monitoring plan will include reviewing the data from the study on a quarterly basis. Items to be reviewed will include: subject eligibility, adherence to treatment plan, documentation of dropouts, evaluation of endpoints, adverse events and/or problems with informed consent.*

***Data Management and Confidentiality***

***Example:*** *Patient data will be entered into electronic spreadsheets. One spreadsheet (the correlation tool) will contain the patient name, medical record number, and patient study number. The second spreadsheet will contain the patient study number, as well as all of the variables required by the study. The two spreadsheets will be stored as separate files, protected by unique passwords. Only the investigators will have access to the files and their passwords. Paper records will be stored in hard copy in a locked filing cabinet in the investigator’s office for a minimum of five years, while electronic records will be store in a password protected file on the investigator’s password protected work laptop. At this time the information will be destroyed in accordance with the General Hospital and/or Baby Grand Pals records protocols.*

***Provisions to Protect the Privacy Interests of Subjects***

***Example:*** *Patient consent and all other research related activities will take place in a private exam room.*

***Medical Care and Compensation for Injury***

***Example:*** *If patients are injured or made sick from taking part in this research study, medical care will be provided. No funds have been set aside to pay the patient in the event of a research related injury. The patients will be instructed to contact the investigator for more information.*

***Funding Source:***

***Example:*** *No funding is being sought for this study.*

***References:*** Use this section to provide all of the references used throughout your study. Pick a format from your favorite journal and use it consistently.

***Example:***

1. Strecker T, Rosch J, Horch RE, Weyand M, Kneser U: Sternal Wound Infections following Cardiac Surgery: Risk Factor Analysis and Interdisciplinary Treatment. Heart Surg Forum 2007:10:E366 - E371.

2. Song DH, Lohman RF, Renucci JD, Jeevanandam V, Raman J: Primary sternal plating in high-risk patients prevents mediastinitis. Eur J Cariothorac Surg 2004:26:367-372.

3. Wu LC, Renucci JD, Song DH: Sternal Nonunion: A Review of Current Treatments and a New Method of Rigid Fixation. Ann Plast Surg 2005:54:55-58.

4. Gottlieb LJ, Pielet RW, Karp RB, Krieger LM, Smith DJ, Deeb GM: Rigid Internal Fixation of the Sternum in Postoperative Mediastinitis. Arch Surg 1994:129:489-493.

5. Hendrickson SC, Koger KE, Morea CJ, Aponte RL, Smith PK, Levin LS: Sternal Plating for the Treatment of Sternal Nonunion. Ann Thorac Surg 1996:62:512-518.